

EXHIBIT 7

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Subject: Re: (BN) FDA Chief Says Agency Must Do More to Stop Abuse of Opioids

Mandatory prescriber education is exactly what we and the twenty-some-odd branded and generic companies proposed to the Agency and its combined Advisory Committees back in 2010 in the context of the soon to be requested Extended-Release / Long-Acting opioid REMS. Scott was consulting at that point and I believe was a supporter of this proposal. Legislation was drafted that would tie the required education to DEA application and/or renewal of prescribing privileges. I believe this is exactly where things are headed, 7 years later.

Sent from my iPad

On Jul 10, 2017, at 17:56, Sackler, Mortimer D.A. [REDACTED] > wrote:

FDA Chief Says Agency Must Do More to Stop Abuse of Opioids

By Anna Edney

- Regulator to require drugmakers to offer prescriber education
- Immediate-release opioids make up 90 percent of prescriptions

(Bloomberg) --

The U.S.'s top drug regulator said on Monday that more must be done to stem the country's tide of opioid addiction, proposing new guidelines and restrictions on some of the most widely used pain pills.

Food and Drug Administration Commissioner Scott Gottlieb laid out plans to have drugmakers conduct doctor education programs on immediate-release opioids, which account for 90 percent of the 200 million opioid painkiller prescriptions written in the U.S. each year. The agency is also exploring whether pain-management training should be required for doctors as well as nurses, pharmacists or other health-care providers.

“America is simply awash in immediate-release opioid products,” Gottlieb said at a speech in Silver Spring, Maryland, as part of a two-day public FDA meeting on painkiller abuse.

“Many people who become addicted to opioids will eventually move on to seek higher dose formulations of these drugs or illicit street drugs, which are increasingly the low-cost alternatives,” Gottlieb said.

Gottlieb said the FDA also plans to survey doctors to make sure the term “abuse deterrent” isn’t giving a false sense of security that the painkillers are less likely to lead to addiction than pills without the designation. Abuse-deterrent versions of the pain pills are formulated to be harder to crush, snort or inject for a more potent high.

“We don’t want to improperly convey a perception that a product that’s resistant to manipulation and abuse is somehow also less prone to fueling addiction when that’s simply not true,” Gottlieb said.

Extended Release

The agency has already acted on related concerns under Gottlieb. Last week, Endo International Plc said it would halt U.S. sales of its powerful opioid painkiller Opana ER, after the FDA said the abuse-deterrent version of the drug had been tied to an outbreak of HIV and hepatitis C after users would inject it and share dirty needles.

Most of the opioids the FDA approves with abuse-deterrent features are extended-release versions. The regulator previously had criticized Endo’s abuse-deterrent technology and didn’t grant it the ability to claim abuse deterrence on the label.

The prescriber education the FDA intends to require for fast-acting opioids would help health-care providers better understand which patients are best suited for the drugs. The FDA recently proposed updating its “blueprint” for pain management education to include non-medication-based therapies including physical therapy, surgery and acupuncture. The FDA already requires prescriber education for extended-release opioids.

The FDA has said it will be examining whether it should take action to reduce the number of 30-day prescriptions that are written for pain related to conditions such as dental procedures that don’t require a whole month’s supply.

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3400398Z US (HHS Food & Drug Administration)

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Regards,

Mortimer